

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

This Document Relates to All Actions

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

**TPP TRIAL DEFENDANTS' REPLY IN SUPPORT OF OMNIBUS
MOTION FOR SUMMARY JUDGMENT**

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Plaintiffs’ omnibus opposition brief (“Opp.”) essentially argues that because they believe (incorrectly) that their “affirmative summary judgment submissions” establish that Defendants’ life-saving VCDs were “contaminated” with NDMA or NDEA (Opp. at 1), they are entitled to summary judgment on all of their claims (except the implied warranty claims, which they abandon). This argument would have the Court abrogate *prima facie* elements of Plaintiffs’ claims, including pre-suit notice, causation/reliance and injury. Plaintiffs also argue that Defendants “ignore and/or attempt to re-litigate decisions rendered by this Court” with regard to some of these elements at the pleading stage (Opp. at 1-2), but that is a “critical misapplication of the fundamental distinction between a motion to dismiss under Rule 12(b)(6) and a motion for summary judgment under Rule 56.” *Wiest v. Tyco Elecs. Corp.*, 812 F.3d 319, 330 (3d Cir. 2016). The Court’s Rule 12 rulings merely afforded Plaintiffs an opportunity to offer evidence in support of their claims. As the Third Circuit explained in *Wiest*, summary judgment is the time to “put up” the evidence supporting claims or be dismissed, and Plaintiffs have not “put up” the evidence needed to proceed to trial.

ARGUMENT

Because the Court ruled that Plaintiffs’ claims are governed by “the law[s] of [their] home state[s]” (ECF [818](#) at 10) but ultimately defined the subclasses in terms of where the subclass members paid for valsartan (which may or may not be their

home states), it is impossible to determine what law governs each subclass member's claim, much less proceed with any trial. (*See* Mem. at 7-8.) Plaintiffs do not address this fundamental problem until page 42 of their opposition brief, asserting that “[t]here is no disconnect” because the Court’s choice-of-law determination was made “at the Rule 12(b)(6) stage before any facts were in the record”—and the facts now supposedly support “defining a class by reference to where the transaction or payment occurred.” (Opp. at 42.) This argument cannot be reconciled with Plaintiffs’ repeated reliance on the Court’s rulings made at the pleading stage. In any event, choice-of-law principles do not change at different stages of the proceedings. Plaintiffs have not identified any “facts in the record” that justify any departure from the initial ruling, and the Court has not performed any new choice-of-law analysis purporting to alter or supplant the original one.¹ Nonetheless, even if the claims were governed by the jurisdictions identified across the three subclasses, Plaintiffs have failed to withstand Defendants’ arguments under those laws.

I. PLAINTIFFS’ EXPRESS WARRANTY CLAIMS FAIL.

A. Plaintiffs’ Express Warranty Claims Fail For Lack Of Notice And Are At Least Partially Stale.

Plaintiffs’ arguments regarding pre-suit notice and timeliness all fail.

¹ Plaintiffs’ contention that Defendants “agreed to the subclass groupings for purposes of class notice” (Opp. at 41), ignores that Defendants expressly “reserve[d] their objections to class certification” (ECF [2532](#) at 2 n.2).

First, Plaintiffs argue (relying on irrelevant cases)² that the U.C.C.’s pre-suit notice requirements do not apply in federal court. (Opp. at 3.) This argument contravenes the legion of federal caselaw routinely applying this element. (*See* ECF [2261-1](#) at F-9, F-26 to F-27, F-32 to F-50; ECF [2261-2](#) at G-45, G-48 to G-53.)

Second, Plaintiffs alternatively argue that the Court “already found Plaintiffs provided pre-suit notice” based on Defendants’ voluntary recalls and their receipt of various pre-suit notice letters. (Opp. at 6.) But the Court’s Rule 12 ruling merely held that Plaintiffs had satisfied “any formal pre-suit pleading requirements.” (ECF [775](#) at 12.) Emblem’s testimony that it was not aware that it or any other TPP provided pre-suit notice (SUMF ¶ 112), demonstrates that Plaintiffs have no evidence to support any notice-related allegations. Plaintiffs cannot compensate for this lack of evidence by relying on recall notices, which did not “apprise[] [Defendants] of the trouble with the particular product purchased by a particular buyer.” *In re Ford Motor Co. Speed Control Deactivation Switch Prods. Liab. Litig.*, MDL No. 1718, 2007 WL 2421480, at *6 (E.D. Mich. Aug. 24, 2007) (citation

² Plaintiffs’ cases involved fundamental conflicts between procedural state-law requirements and the Federal Rules of Civil Procedure. *See, e.g., Albright v. Christensen*, 24 F.4th 1039, 1042, 1046 (6th Cir. 2022) (“presuit-notice rules for medical-malpractice actions” do not apply in federal courts because they “conflict” with Federal Rule of Civil Procedure 3); *Pledger v. Lynch*, 5 F.4th 511, 523-34 (4th Cir. 2021) (West Virginia Medical Professional Liability Act’s “pre-dispute certificate requirement . . . is displaced by the Federal Rules”) (citation omitted). Here, by contrast, there is no conflict between the states’ substantive requirement to notify the seller of a breach and any federal rule or practice.

omitted). Nor can Plaintiffs manufacture a factual question regarding notice by highlighting “pre-suit notice letters,” only one of which was served by a “TPP class member,” two years after MSP initiated its TPP lawsuit. (Opp. at 7-8.)

Third, Plaintiffs argue that they satisfied any notice requirement by serving a “comprehensive pre-suit notice letter” on Defendants prior to filing their Third Amended Complaint (*id.* at 9), but that occurred nearly three years after MSP commenced its original lawsuit, further highlighting Plaintiffs’ failure to provide any *pre*-suit notice. (See ECF [2601](#) at Ex. 103 (Teva-103).) The only authority Plaintiffs cite supporting this approach to notice was recently criticized for effectively abrogating an essential element of New York warranty law and should not be followed. See *Wheeler v. Topps Co.*, 652 F. Supp. 3d 426, 432-33 (S.D.N.Y. 2023) (criticizing *Bayne v. Target Corp.*, 630 F. Supp. 3d 544, 550 (S.D.N.Y. 2022)) (allowing any pleading to satisfy the notice requirement “does not make sense” in light of the plain language “requir[ing] a buyer to provide notice of the breach . . . ‘or be barred from any remedy’”) (quoting N.Y. U.C.C. § 2-607(3)(a)).

Fourth, Plaintiffs also argue that, at a minimum, the question of notice is a “fact question for the jury.” (Opp. at 9.) However, in the cases cited by Plaintiffs (many of which were decided on the pleadings), there was no dispute that the plaintiffs had actually provided some pre-suit notice; rather, the parties disagreed on the “sufficien[cy]” of such notice. See *Jarrett v. Panasonic Corp. of N. Am.*, 8 F.

Supp. 3d 1074, 1083 (E.D. Ark. 2013) (“[I]t is a question of fact whether [p]laintiff seeking to return, exchange, or have repaired . . . and . . . calling Sanyo and Wal-Mart to complain . . . was sufficient pre-suit notice”). Here, by contrast, Plaintiffs have no evidence that any TPP subclass member provided any pre-suit notice of an alleged breach of warranty.³

Finally, Plaintiffs appear to concede that claims before “December 14, 2014” would be stale absent application of a discovery rule or some kind of equitable tolling—the former of which Plaintiffs acknowledge is not recognized in the vast majority of relevant states. (*See* Opp. at 11-16.) To the extent some of the relevant states even recognize fraudulent concealment or equitable tolling for claims for breach of warranty, such doctrines are clearly inapplicable to Plaintiffs’ theory that Defendants failed to “identify and disclose the contamination” (*id.* at 15) because it is the “same act that forms the basis for the claim.” *Fertitta v. Knoedler Gallery, LLC*, No. 14-CV-2259, 2015 U.S. Dist. LEXIS 10419, at *24 (S.D.N.Y. Jan. 29, 2015) (citation omitted). And as Plaintiffs’ authority recognizes, the continuing

³ Plaintiffs also urge the Court to reject Defendants’ notice argument based on principles of “[e]quity and [e]stoppel.” (Opp. at 10 (quoting N.Y. U.C.C. § 1-103 (“[P]rinciples of law and equity, including . . . estoppel . . . supplement its provisions.”))). Plaintiffs do not cite a single case applying this general provision, which is clearly not a catchall exception to the essential element of notice. Courts sitting in diversity must apply “the current law . . . and leave it undisturbed,” rather than expand it. *City of Philadelphia v. Lead Indus. Ass’n*, 994 F.2d 112, 123 (3d Cir. 1993).

violation doctrine for warranty claims merely provides that a stale “first breach of duty or instance of misconduct” does not “bar suit for any subsequent breach of misconduct”—which logically cannot resuscitate the pre-2014-based claims. *Aryeh v. Canon Bus. Sols., Inc.*, 292 P.3d 871, 879-80 (Cal. 2013).

B. Plaintiffs Have No Evidence That Any Express Warranty Existed, Was Breached Or Was Relied On.

The crux of Plaintiffs’ arguments regarding the existence of an express warranty, breach and reliance is that the “Court has already ruled in favor of Plaintiffs” on these issues. (Opp. at 17.) But the Court merely found that Plaintiffs had adequately pled a warranty claim, “accept[ing] all factual allegations as true” and “afford[ing] [Plaintiffs] an opportunity to offer evidence in support of their claims.” (ECF [775](#) at 10 (citations omitted).) At this more advanced stage, the undisputed record disproves Plaintiffs’ allegations on these essential elements.

Existence of express warranties. Plaintiffs seek to minimize the import of SummaCare’s and Emblem’s testimony on the ground that it “failed to address the facts in a thorough or directly relevant way.” (Opp. at 18.) But that testimony—e.g., that SummaCare had *no* “warranties in place” with Defendants (SUMF ¶¶ 84-85)—speaks for itself and should be dispositive. Plaintiffs’ reliance on Dr. Panagos’ so-called “exposition of the Orange Book” cannot fill this void because the Court precluded her opinions on this subject, only permitting her to provide “background” on the workings of TPPs and P&T Committees. (See ECF [2261](#) at 94; see also ECF

[2581](#) at 23.) And Plaintiffs’ reliance on Dr. Conti’s vague testimony about unidentified “assurance[s] of safety and quality” (Opp. at 20 (citation omitted)) (an issue that is, in any event, outside her expertise) is similarly unavailing because it reflects generalized views about TPPs in the abstract, which cannot change the unequivocal statements from the actual company witnesses in this case.

Breach. Plaintiffs argue that Defendants breached a supposed warranty that the VCDs were the “chemical equivalent of the Orange Book pharmaceutical” by dint of their voluntary “recall” of the medications. (*Id.* at 18, 21 (citation omitted).) But “a warning letter and a voluntary recall notice do not establish an applicable standard of care,” let alone suffice to prove a breach of such a standard. *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 497 (W.D. Pa. 2012). Plaintiffs also argue that Defendants breached the USP’s requirement that manufacturers “use . . . whatever means . . . necessary to identify and address any impurities that resulted.” (Opp. at 21 (citation omitted).) As the FDA has explained, however, “it needs to be recognized that the risk of an impurity can occur in order to know that it should be tested for” (SUMF Ex. 64, Aug. 2018 Gottlieb Statement)—a standard Plaintiffs cannot establish given the FDA’s finding that the presence of NDMA was “not anticipated” prior to 2018. (*Id.*)

Reliance. Plaintiffs argue that the Court “has already held that ‘Plaintiffs . . . did not have to “perceive” the package labelling or insert in order to create a benefit

of the bargain” (Opp. at 21-22 (quoting ECF [775](#) at 14)) when, in fact, the Court merely held that Plaintiffs had “sufficiently pleaded” that element (ECF [775](#) at 14). Discovery has now shown that Plaintiffs cannot prove reliance because Emblem and SummaCare were not even aware of the existence of any purported warranties. (*See, e.g.*, SUMF ¶¶ 84-85.) Plaintiffs also assert that Defendants’ Statement of Facts “concedes” that P&T Committees “rely on . . . FDA-approved package inserts” and “the product label” (Opp. at 22 (quoting SUMF ¶ 122)), but those materials necessarily matched the ones that accompanied branded valsartan (SUMF ¶ 120).

II. THE CLASS MEMBERS’ FRAUD-BASED CLAIMS FAIL.

Plaintiffs’ various arguments regarding falsity, reliance and other elements of their fraud-based claims lack merit.

First, Plaintiffs argue that Defendants misrepresented that the VCDs were FDA-approved valsartan, citing testimony from a ZHP corporate representative that “Prinston and Solco have always represented” that their valsartan products were the therapeutic equivalent of the brand-name product (Opp. at 25 (citation omitted)), and highlighting statements from the Orange Book about therapeutic equivalence (*see id.* at 25-26). But none of that is evidence that Defendants’ VCDs were not therapeutically equivalent to the branded medication. Plaintiffs also highlight the FDA’s warning letter (*see id.* at 26 (citing Pls.’ Opp. to SUMF ¶ 61)), which, as previously discussed, is not sufficient evidence that Defendants breached any

warranty, much less engaged in fraud. And Plaintiffs’ reliance on their experts’ opinions that the VCDs “did not meet USP specifications” (*id.*), similarly does not suffice to establish falsity because Plaintiffs have conceded that the USP did *not* contain any standard relating to NDMA or NDEA in VCDs before 2018 (ECF [2569-1](#) at 23); indeed, even today, the USP does not prohibit trace amounts of nitrosamines (SUMF ¶¶ 70, 76).⁴

Second, Plaintiffs argue that the Court “has already found” that the TPP subclass members “had no choice but to ‘rely’” on Defendants’ labeling representations (Opp. at 27 (quoting ECF [775](#) at 14)); this argument once again misapprehends the nature of the Court’s Rule 12 ruling, which preceded undisputed testimony from SummaCare and Emblem disproving reliance (SUMF ¶¶ 83-84). Although Plaintiffs also argue that the two assignors “block[ed]” the VCDs after the voluntary recalls (Opp. at 27), that says nothing about what (if anything) they relied on in deciding to pay for the medicines in the first place. And Plaintiffs’ claim that the “TPP Plaintiffs . . . rely on the labeling” (*id.*), rests on the same excluded testimony from Dr. Panagos and generic statements about P&T Committees that

⁴ Although Plaintiffs contend that Defendants are not seeking summary judgment under the “unfair” prongs of the relevant consumer-protection statutes (Opp. at 27-28), this Court has recognized that Plaintiffs’ common-law fraud and consumer-fraud claims are both based on “affirmative misrepresentations” and “material omissions” (ECF [818](#) at 12). Accordingly, any alleged “unfairness” theory of consumer-protection liability is encompassed by Defendants’ arguments.

Defendants previously explained cannot survive summary judgment.

Third, Plaintiffs’ other arguments regarding their consumer-protection claims also fail. Plaintiffs try to manufacture standing under Hawaii law by recasting their claims as being rooted in “unfair competition” (not consumer fraud), but their own authority dismissed such a theory on the pleadings where, as here, the plaintiff failed to “allege how a defendant’s ‘conduct will negatively affect competition.’” *BlueEarth BioFuels, LLC v. Hawaiian Elec. Co.*, 780 F. Supp. 2d 1061, 1074 (D. Haw. 2011) (citation omitted). Plaintiffs also contend that they can sue under Missouri’s statute because the VCDs were “intended for personal consumption by” their beneficiaries (Opp. at 33), even though Judge Martinotti rejected a virtually identical argument by MSP in another case. *See MSP Recovery Claims, Series, LLC v. Sanofi Aventis U.S. LLC*, No. 18-cv-2211, 2019 WL 1418129, at *18 (D.N.J. Mar. 29, 2019). And although Plaintiffs argue that Louisiana’s and Montana’s substantive prohibitions against classwide consumer-protection remedies are inapplicable in federal court under the plurality opinion in *Shady Grove Orthopedic Associates, P.A. v. Allstate Insurance Co.*, 559 U.S. 393, 410 (2010), they misconstrue prior Third Circuit law, which even Plaintiffs’ authority recognizes did “not apply *Shady Grove* to Rule 23 or class-action bars contained within state statutes.” *Amato v. Subaru of Am., Inc.*, No. 18-16118, 2021 WL 2154976, at *8 (D.N.J. May 27, 2021).

III. PLAINTIFFS CANNOT ESTABLISH A COGNIZABLE INJURY.

Although Plaintiffs contend that the Court “already has rejected” Defendants’ injury challenge (*see* Opp. at 37), those decisions expressly recognized that Plaintiffs’ theory that the VCDs were “worthless” was “opaque,” may not be “legally correct” and presented a “merits” question that could not be resolved at the motion-to-dismiss or class-certification stages. (ECF [728](#) at 3, 5, 8, 11-12, 14-15; ECF [2261](#) at 89.) At this stage of the litigation, the Court should finally determine that the “worthlessness” theory being touted by Dr. Conti is not viable as a matter of law or economics. And while Plaintiffs assert that Dr. Conti’s recent testimony is “consistent” with her claim that the VCDs were worthless, that testimony makes clear that the efficacy of a medication necessarily “affect[s] its economic value” (SUMF ¶ 129 (citation omitted)), undermining her “worthlessness” opinion.

IV. PLAINTIFFS CANNOT PROVE THAT DEFENDANTS’ ALLEGED CONDUCT PROXIMATELY CAUSED ANY INJURY.

Plaintiffs argue that the Court should allow a jury to decide causation based on two outlier First Circuit cases that have been criticized by other courts for ignoring the “many layers” that separate a pharmaceutical manufacturer’s alleged misconduct and a TPP’s payment decisions. *See Sidney Hillman Health Ctr. of Rochester v. Abbott Lab’ys*, 873 F.3d 574, 578 (7th Cir. 2017) (“the causal chain is too long”) (criticizing *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21 (1st

Cir. 2013)).⁵ Indeed, one of those courts affirmed the grant of summary judgment in Defendants’ primary authority, *Sergeants Benevolent Ass’n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 20 F. Supp. 3d 305, 311 (E.D.N.Y. 2014), *see* 806 F.3d 71 (2d Cir. 2015). Plaintiffs seek to distinguish *Sergeants* on the ground that it “did not involve a contaminated or adulterated drug” (*see* Opp. at 36), but the reasoning underlying that case—that proving causation in TPP cases involving long chains of causation is nearly “impossible”—also applies here. *Sergeants*, 806 F.3d at 97. Regardless of how Plaintiffs try to frame their case, it boils down to the core allegation that the VCDs allegedly contained trace amounts of purportedly “genotoxic impurities” (Opp. at 1), which is a “safety”-based theory that necessarily implicates a long and attenuated chain of causation. *Sergeants*, 806 F.3d at 92.

V. PLAINTIFFS DO NOT HAVE EVIDENCE TO SUPPORT A COGNIZABLE DAMAGES THEORY.

A. Plaintiffs’ Damages Model Cannot Establish Damages On A Classwide Basis.

Dr. Conti’s “point of sale” damages model is mismatched both to the “point of payment” subclasses certified for trial and the Court’s home-state choice-of-law

⁵ Plaintiffs’ cases are also inapposite. In *In re Neurontin Marketing & Sales Practices Litigation*, 712 F.3d 21 (1st Cir. 2013), the TPP offered evidence that “*its* employees *directly* relied on Pfizer’s misrepresentations in preparing monographs and formularies, which, in turn, influenced doctors’ prescribing decisions,” *id.* at 40 (emphases added). And in *In re Celexa & Lexapro Marketing & Sales Practices Litigation*, 915 F.3d 1 (1st Cir. 2019), “the district court did not consider the issue of causation in its summary-judgment ruling,” *id.* at 12.

ruling. (Mem. at 31-34.) Plaintiffs respond that Defendants “waived” this argument by failing to raise it at “any prior stage” (Opp. at 40), but that makes no sense since these fundamental mismatches did not come to light until *after* the Court granted Plaintiffs’ motion for class certification and adopted the subclasses for trial (*see* ECF [2343](#)). Indeed, because Plaintiffs’ motion for class certification sought a *nationwide* TPP class, their request implicated every jurisdiction; by contrast, the subclasses ultimately defined by the Court expressly exclude multiple states, creating a very significant risk of recoveries for TPPs that paid for VCDs outside of the subclass states and whose claims are governed by other states’ laws.

Plaintiffs’ position on the merits also fails. Plaintiffs falsely assert that defense expert, Wayne Gibson, “agree[s]” that the location of the “point of sale” is interchangeable with where each TPP “paid any amount of money” (Opp. at 40 (citation omitted)), even though Mr. Gibson repeatedly made it clear that he does *not* agree that TPPs pay at the point of sale. (*See* Teva Resp. to Pls.’ Suppl. SUMF ¶ 2.) Plaintiffs also highlight the fact that the Retailer Defendants describe the amounts relied upon by Dr. Conti as “Ins[urance] P[ai]d” (Opp. at 41), but the redacted documents they cite merely confirm that the amounts “Patient Paid” and the amounts “Ins Paid” are distinct transactions (ECF [2432](#) at 2).⁶

⁶ Plaintiffs cannot prove any fraud- or warranty-based damages in any event. Plaintiffs argue that the relevant state laws do not vary in how they measure damages under these causes of action, purporting to rely on the Court’s “exhaustive[]

B. Plaintiffs Are Not Entitled To Punitive Or Exemplary Damages.

Finally, with respect to punitive damages, Plaintiffs assert that, under New Jersey’s “most significant relationship” test, the relevant state laws are “not their home states, but the states where VCDs were purchased.” (Opp. at 44.) Plaintiffs do not cite a single case endorsing their argument, and it is at odds with the Court’s prior choice-of-ruling broadly holding that “the law of each plaintiffs’ home state should be applied” to all claims, as well as Defendants’ caselaw applying this principle to punitive damages. (ECF [818](#) at 10.) *See Gorji v. C.R. Bard, Inc.*, No. 21CV3134, 2022 U.S. Dist. LEXIS 34765, at *1 (D. Neb. Feb. 28, 2022). In any event, Plaintiffs do not identify any—much less clear and convincing—evidence of the kind of “malicious,” “willful and wanton” misconduct that they concede is required for punitive damages under any standard. (Opp. at 48.) Instead, they reference their “Defendant specific briefs,” which accuse ZHP and Torrent of knowing that the VCDs contained trace amounts of NDMA and Teva of being aware of purported CGMP violations. (*Id.* at 48-50.) Even if there were any truth to those claims (and there is not, for the reasons detailed *infra*), it clearly does not rise to the

analy[sis]” of this issue at class certification (*see* Opp. at 39), even though the class certification opinion does not address the applicable state law governing damages (*see generally* ECF [2261](#)). Putting aside that there are fundamental differences among the states on the measure of damages, *In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 299 F. Supp. 3d 430, 578-79 (S.D.N.Y. 2018) (such variations “weigh against” certification), Plaintiffs cannot satisfy any standard for the same reasons that Plaintiffs cannot establish a cognizable injury.

level of “malicious or wanton[]” misconduct. *See DeGennaro v. Rally Mfg. Inc.*, No. 09-443, 2011 WL 5248153, at *6-7 (D.N.J. Nov. 2, 2011) (granting summary judgment on punitive damages where “[d]efendants believed that the [product at issue] was a safe product”). Accordingly, Defendants are entitled to summary judgment on Plaintiffs’ request for punitive damages.

VI. PLAINTIFFS’ RESPONSES TO THE DEFENDANT-SPECIFIC MOTIONS FOR SUMMARY JUDGMENT ALSO FAIL.

A. Plaintiffs Fail To Refute The ZHP Defendants’ Arguments.

Plaintiffs cannot refute that their express warranty, fraud and consumer-protection claims against ZHP and Huahai fail because neither company made statements about VCDs. (ZHP Mem. at 3-6.) Plaintiffs argue that, because the VCDs marketed and sold by Princeton/Solco were manufactured at a ZHP plant, ZHP is responsible for all statements in the product label and packaging. (ZHP Opp. at 1-2.) But Plaintiffs have not identified any caselaw holding that a contract manufacturer of a product sold by another entity is liable for marketing statements about the product. Further, Plaintiffs’ assertion that ZHP “prepared and approved” the package and label for the VCDs (*id.*) is belied by the documents they cite, which state that Princeton provided the “specifications for all packaging and labeling components.” (*See, e.g.,* ZHP Ex. 147 (PRINSTON00463638) at 12 (cited in Pls.’ Opp. to SUMF ¶ 3 (in turn cited in ZHP Opp. at 1-2)).) Plaintiffs’ argument that ZHP and Huahai made representations to the “downstream supply chain” that were

“directed at the purchasers of the VCDs” by submitting a Drug Master File (“DMF”) for valsartan API to the FDA (ZHP Opp. at 3) similarly fails because a DMF is a highly confidential regulatory filing that is not accessible to the public or other industry members.⁷ Thus, statements in a DMF could not possibly be directed at consumers of VCDs, much less the TPPs that pay for them. And Plaintiffs’ argument that ZHP, Princeton and Solco should be treated as one entity for purposes of liability for fraud- or warranty-based claims simply because they are related entities that share certain executives (ZHP Opp. at 3-4) seeks to upend longstanding principles regarding corporate separateness. *See, e.g., Linus Holding Corp. v. Mark Line Indus., LLC*, 376 F. Supp. 3d 417, 426-27 (D.N.J. 2019) (declining to pierce corporate veil absent evidence that subsidiary “operated as a sham or a dummy corporation”; “it is well-established that ‘common ownership and common management alone’” is “insufficient for veil-piercing purposes”) (citation omitted).

Plaintiffs’ common-law fraud claims fail for lack of scienter. As anticipated, Plaintiffs insist that a 2017 email from ZHP employee Jinsheng Lin shows that ZHP had knowledge of the potential for NDMA as an impurity in valsartan API. (ZHP Opp. at 7-9.) But the email as a whole—including its attachment of a patent unrelated to valsartan API—makes clear that Mr. Lin’s email addresses a potential impurity

⁷ *See* FDA, Drug Master Files (DMFs), <https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs> (last updated Nov. 3, 2023).

in *Irbesartan*, a different drug molecule with no relevance to this case. (ZHP Mem. at 9.) Further, Plaintiffs fail to dispute that, even if the email raised a question of fact as to scienter, Plaintiffs’ fraud claims, and alleged damages, would be limited to VCD purchases between July 2017 and the recall in July 2018.⁸

B. Plaintiffs Fail To Refute Teva’s Arguments.

Scienter/malice. Plaintiffs concede Teva had *no knowledge* of any NDMA impurity in ZHP’s API until June 20, 2018. (Teva Mem. at 6-8; *compare* Pls.’ Teva Opp. at 4-7.) Plaintiffs nevertheless assert that “[p]lenty of evidence” shows Teva knew of related CGMP violations (Pls.’ Teva Opp. at 4-5); that claim is foreclosed by the record, as Teva has shown (*see* ECF [2602](#) ¶¶ 1-5, 42-81). Regardless, Plaintiffs at most suggest that a jury might “infer” (Pls.’ Teva Opp. at 5) that Teva should have known of the existence of the NDMA impurity—which cannot defeat summary judgment because “‘actual knowledge’ of the falsity” is the “essential element” of fraud; “should have known” is “not enough” to satisfy scienter. *WESI, LLC v. Compass Env’t, Inc.*, 509 F. Supp. 2d 1353, 1359 (N.D. Ga. 2007) (quoting *Hertz Corp. v. Cox*, 430 F.2d 1365, 1375 (5th Cir. 1970)). (*See also* Teva Mem. at

⁸ Defendants have shown that Plaintiffs’ claims against them also fail because the FDA never deemed any VCDs sold by them adulterated or misbranded. (ZHP Mem. at 6-7; Teva Mem. at 4-6; Torrent Mem. at 8-10.) Based on the Court’s recent Rule 702 rulings, however, Defendants understand that the Court believes that is a question of fact to be resolved at trial. (*See, e.g.*, ECF [2581](#) at 16-17, 19.) Defendants nevertheless preserve both this argument and their challenges to the Court’s order on the admission of experts for appeal.

6-7.) Plaintiffs have also failed to present any evidence enabling a jury to “impute” ZHP’s purported knowledge to Teva; as Plaintiffs’ cases recognize, “imputed” knowledge requires an agency or employment relationship. (*See* Pls.’ Teva Opp. at 7-8). Likewise, Plaintiffs’ blanket references to “illustrative examples” and “non-exhaustive facts” (*id.* at 4) cannot overcome their lack of evidence of willful, malicious, or egregious misconduct, as required to recover punitive damages.

Adulteration. As to adulteration, Plaintiffs rely on the Rule 702 Order, which excluded part of one Teva expert’s opinions. (*Id.* at 3.) This argument disregards the *same order’s* ruling that adulteration “is only for the fact-finder to reach.” (ECF [2581](#) at 19.) It also ignores innumerable other material factual disputes regarding adulteration based on other evidence. (*See* ECF [2603](#) at 12-32.)

Personal Jurisdiction. Plaintiffs’ nebulous references to “global procurement,” “quality functions,” Mylan-sourced API, and distinct rulings in unrelated cases (Pls.’ Teva Opp. at 9-10), establish no jurisdictional nexus between Teva Ltd. and any ZHP-sourced VCDs sold in the United States, which are the only products at issue in this case. Nor have Plaintiffs satisfied their burden of proof to take “jurisdictional discovery.” (*Id.* at 8.) *See Toys ‘R’ Us, Inc. v. Step Two, S.A.*, 318 F.3d 446, 458 (3d Cir. 2003).

C. Plaintiffs Fail To Refute Torrent’s Arguments.

Scienter/knowledge. With respect to knowledge, Plaintiffs argue that the

portions of ZHP’s DMF Torrent could access showed the route of synthesis in sufficient detail to understand that nitrosamines could be formed. (ECF [2595](#) at 1-2.) But Plaintiffs admit that “the route of synthesis for C Code valsartan would not suggest high levels of NDMA.” (ECF [2560](#) ¶ 28.) Moreover, all Torrent could see was the part of the DMF that “summarize[d] at a high level” the process of making the API (Nigh Ex. 3, at 117:15-118:11), which Plaintiffs fail to show was sufficient to know nitrosamines might—much less would likely—form. Plaintiffs also point to evidence that Torrent had to ask ZHP about impurity potential, which further belies the notion that Torrent knew (*see* Nigh Ex. 6, at 183:8-184:10; TORRENT-MDL2875-00010187 (Ex. 1 to Cert. of Jessica Davidson))—particularly since Plaintiffs’ expert admits that testing “would not have identified NDMA” unless Torrent was specifically looking for it (SUMF ¶ 71 (citation omitted)). Plaintiffs also cannot dispute that ZHP told Torrent that C code API had “NO Genotoxic impurity potential” on June 25, 2018, further underscoring that Torrent lacked the required knowledge at that time. (ECF [2597](#) ¶ 11.) And Plaintiffs concede that Torrent did not know that *Torrent’s products*—as opposed to ZHP’s API—contained trace amounts of NDMA until August 17, 2018, and initiated its recall within a day. (*See* ECF No. [2560](#) ¶¶ 16, 21; ECF No. [2596](#) at 6-7.) Finally, Torrent’s consideration of the financial implications of its decisions (ECF [2595](#) at 6-8) cannot show knowledge of potential nitrosamine formation, much less intent to defraud. No business ever

makes a decision without considering financial impact. Accordingly, Plaintiffs have failed to identify any evidence that Torrent acted with the requisite knowledge, much less scienter, warranting summary judgment on Plaintiffs' fraud-based claims and their request for punitive damages.⁹

Adulteration. "Claims of adulteration should be resolved by the FDA." *Healthpoint, Ltd. v. Stratus Pharms., Inc.*, 273 F. Supp. 2d 769, 787 (W.D. Tex. 2001). Plaintiffs cite no contrary law, and the Court should not permit a jury to usurp the role of the FDA. Moreover, Plaintiffs' purported evidence of adulteration is disputed. (See ECF [2597](#) ¶ 48.) In particular, the email from Dawn Chitty that Plaintiffs rely upon does not state whether the batches mentioned therein are ZHP API or Torrent finished dose VCDs. (See Nigh Ex. 10.)

CONCLUSION

For the foregoing reasons, as well as those in Defendants' opening briefs, the Court should grant Defendants summary judgment on all of Plaintiffs' claims.

Dated: January 31, 2024

Respectfully submitted,

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⁹ At a minimum, the Court should limit any recovery of punitive damages to Plaintiffs' fraud claims, as Plaintiffs have not opposed Torrent's motion barring punitive damages on Plaintiffs' breach-of-warranty and consumer-protection claims. (See ECF [2595](#) at 8.)

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 31, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ Jessica Davidson
Jessica Davidson